

DATE: 08/12/09

SUBJECT: Product Chemistry Review of OSKU-HELLAS TECHNICAL

FROM: Indira Gairola
Product Chemistry Team
Technical Review Branch/RD (7505P)

TO: Tony Kish / Bryant Crowe PM 22
Fungicide Branch /RD (7505P)

DP BARCODE No.: 367597

Reg. No. 56799-G

COMPANY: PRODUCTOS QUIMICOS Y AILMENTICIOS OSKU S.A

PCC: 111409

Decision No. 219583

Chemical Name: Sodium Metabisulfite

CAS No. 1071-36-6

USE: Fungicide

PRODUCTOS QUIMICOS Y AILMENTICIOS OSKU S.A has submitted partial Product Chemistry Guideline reference 830 Subgroup A & Subgroup B data for OSKU-HELLAS TECHNICAL.

The submitted package was reviewed and details of product chemistry data will be discussed in the following Pages:

SUMMARY OF FINDINGS:

1. PRODUCTOS QUIMICOS Y AILMENTICIOS OSKU S.A has submitted MRID#s 477975-01, 477975-014, 478086-01 and 478086-02 for Product Chemistry Data for OSKU-HELLAS TECHNICAL.
2. The purity for subject product OSKU-HELLAS TECHNICAL is stated as 98.0% of Sodium Metabisulfite.
3. The certified limits are not specified in detail. (as per 40CFR.175 (b) (2)).

- 4 . Product Chemistry Data corresponding Sub Group A and sub group B do not satisfy the data requirements of 40CFR §158.320 to §158.355. for Technical Sodium Bisulfite. Please refer to the Product Chemistry Data Table for subgroup A and sub Group B for details of deficiencies.
5. Applicant has submitted accelerated Storage Stability / Corrosion Characteristics study Data @ $54^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for a period of 14 days. The results revealed no significant changes in physical or chemical properties.

CONCLUSIONS :

TRB has reviewed the product chemistry data submitted for the above mentioned subject product and has concluded that:

1. Product Chemistry data requirements for subgroup A & B are not satisfied completely and do not fulfill the requirement of entire OPP test guidelines.
2. Certified limits along with impurities are not addressed along with reactions for this technical therefore are not in compliance with 40CFR.175 (b) (2).
See CONFIDENTIAL APPENDIX.
3. Average recovery of Sodium Metabisulfite ranged from acceptable level of 99.0%-95.0% Mean Average 99.19%.

Sub Group 'A' Guidelines Series 830.1550-1800 DP BAR CODE: 367597
File Symbol No.: 56799-G PRODUCT NAME: OSKU-HELLAS TECHNICAL

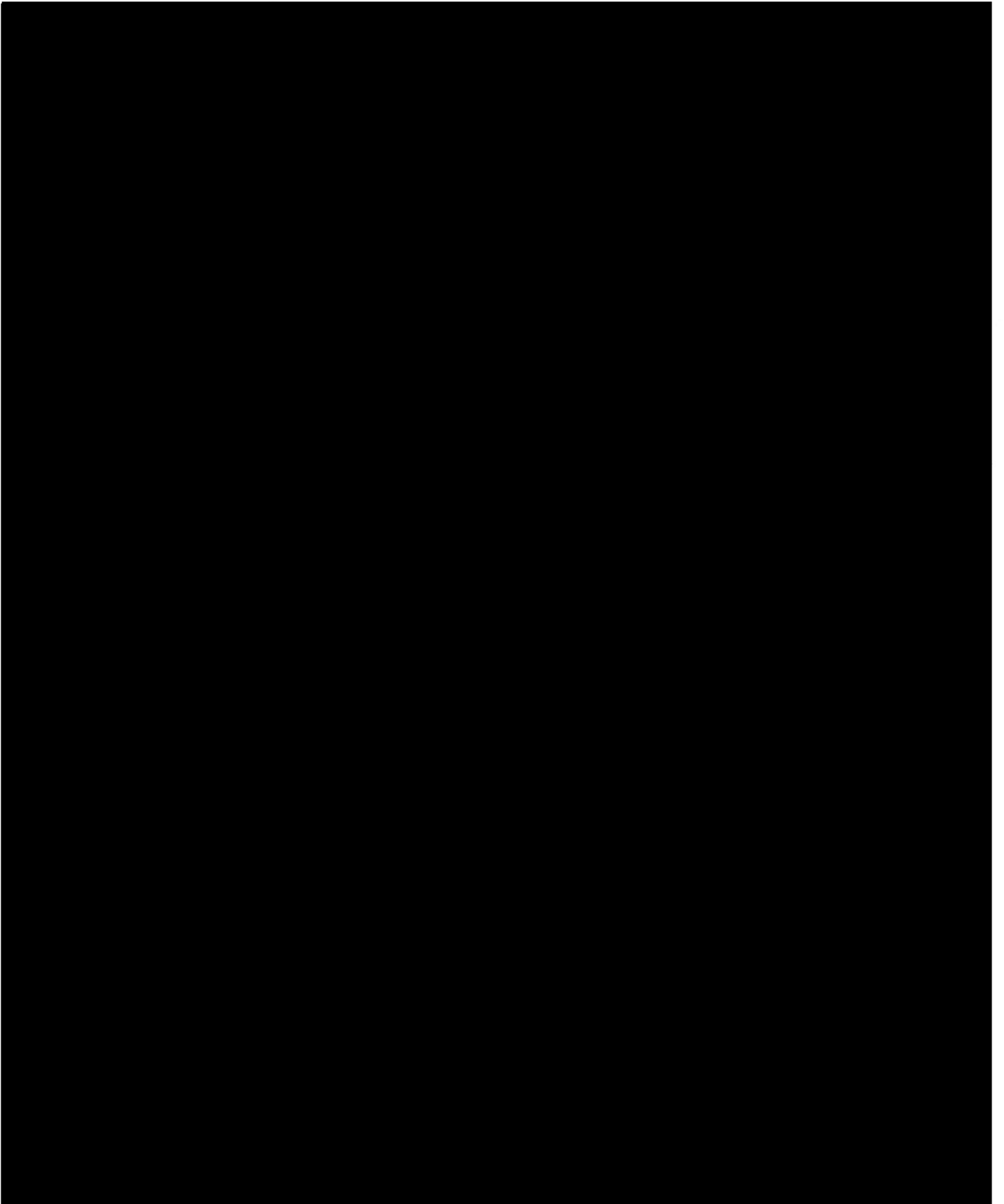
Table 1:Manufacturing and Impurity Data for TECHNICAL				
GLN	Requirement	MRID	Status ¹	Details and/or Deficiency ²
830.1550	Product Identity & Disclosure of Ingredients		G	MRID # 477975-04 along with structural formula is required
830.1600 830.1620 830.1650	Starting Materials & Manufacturing Process		G	MRID # 477975-04 details regarding chemical reactions along with flow chart is required.
830.1670	Discussion of Impurities		G	MRID # 477975-04 entire details regarding chemical reactions is required
830.1700	Preliminary Analysis		A	MRID # 477975-01
830.1750	Certification of Limits		N	Is not defined as per 40CFR 175.(b) (2)
830.1800	Analytical Methods		A	MRID # 477975-01
¹ A = Acceptable; N = Unacceptable G= Data gap (see Deficiency); N/A = Not Applicable. ² Refer to CBI Appendix A for details.				

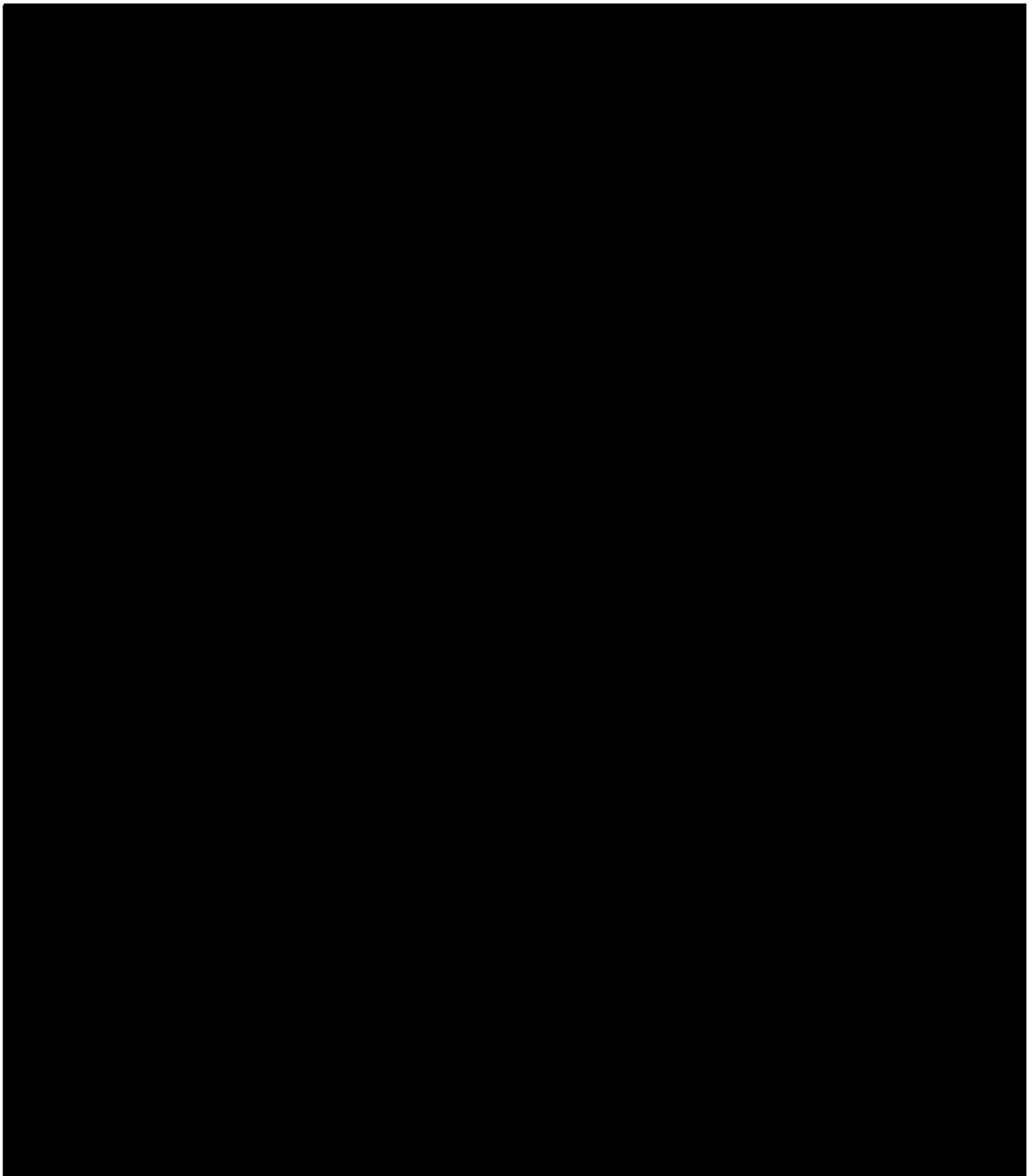
Sub Group B Guidelines Series 830.6302 File Symbol No.: 56799-G
PRODUCT NAME: OSKU-HELLAS TECHNICAL

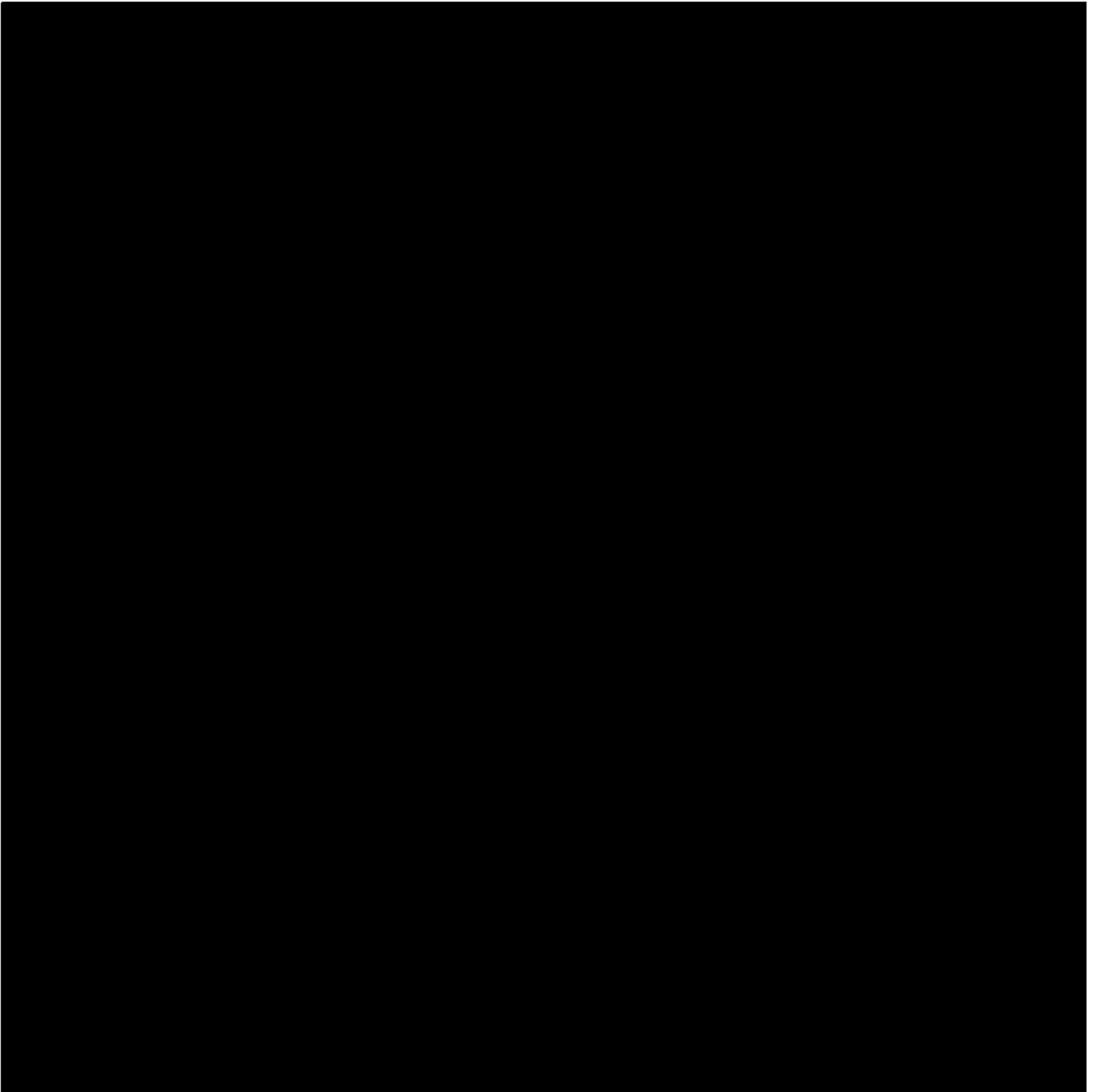
Table 2: Physical and Chemical Properties EPA REG. NO.:				
GLN	Requirement	MRID.	Status ¹	Result ² or Deficiency
830.6302	Color	477975-04	A	Solid
830.6303	Physical State	477975-04	A	White
830.6304	Odor	477975-04	A	Pungent SO ₂ odor
830.6313	Stability		A	Stable on contact with Al, Zn, and their corresponding acetates powder @ 54°C 14 day & @ ambient Temp., unstable on contact with Fe acetate.
830.6314	Oxidation / Reduction	478086-01	A	Non visible reaction with Tetrahydrofuran, KMnO ₄ , Zn, Methanol, methylene chloride, and Hexane @ 20°C when water is added SO ₂ is released and the soln becomes acid.
830.6315	Flammability		G	
830.6316	Explosibility		G	
830.6317	Storage Stability		G	
830.6319	Miscibility		G	
830.6320	Corrosion Characteristics		G	
830.7000	pH	477975-04	A	4.0 (10% soln.)
830.7050	UV/Visible Absorption		G	
	Viscosity	NA	NA	
830.7200	Melting Point/ Melting Range		G	
830.7220	Boiling Point/ Boiling Range	NA	NA	
830.7300	Density/ Relative Density/ Bulk Density	477975-04	A	1.5
830.7370	Dissociation Constant in Water		G	
830.7550	Partition Coefficient (Octanol/Water)		G	
830.7840	Solubility		G	
830.7950	Vapor Pressure		G	
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable, I = incomplete G = Data gap				

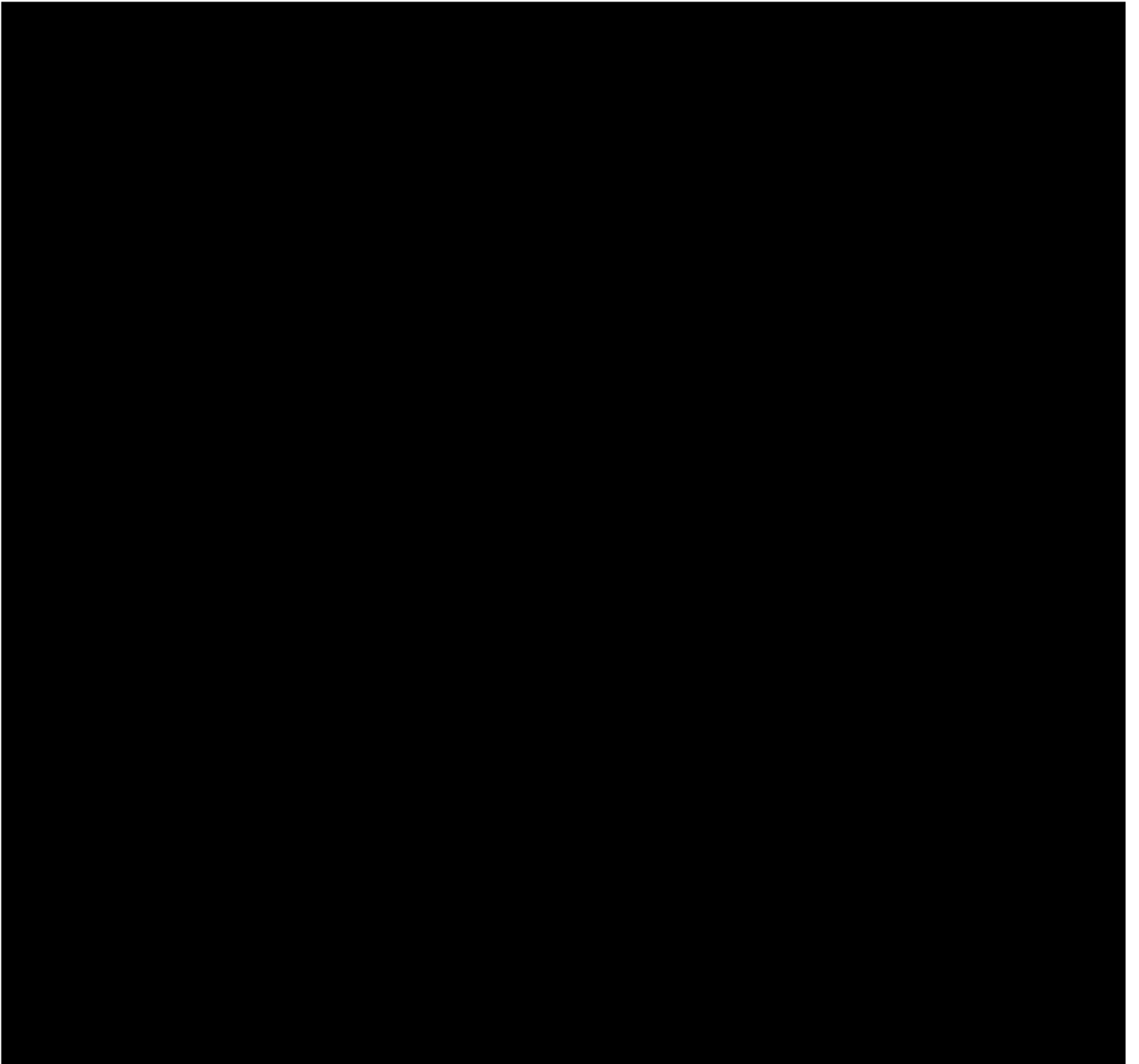
CONFIDENTIAL APPENDIX.

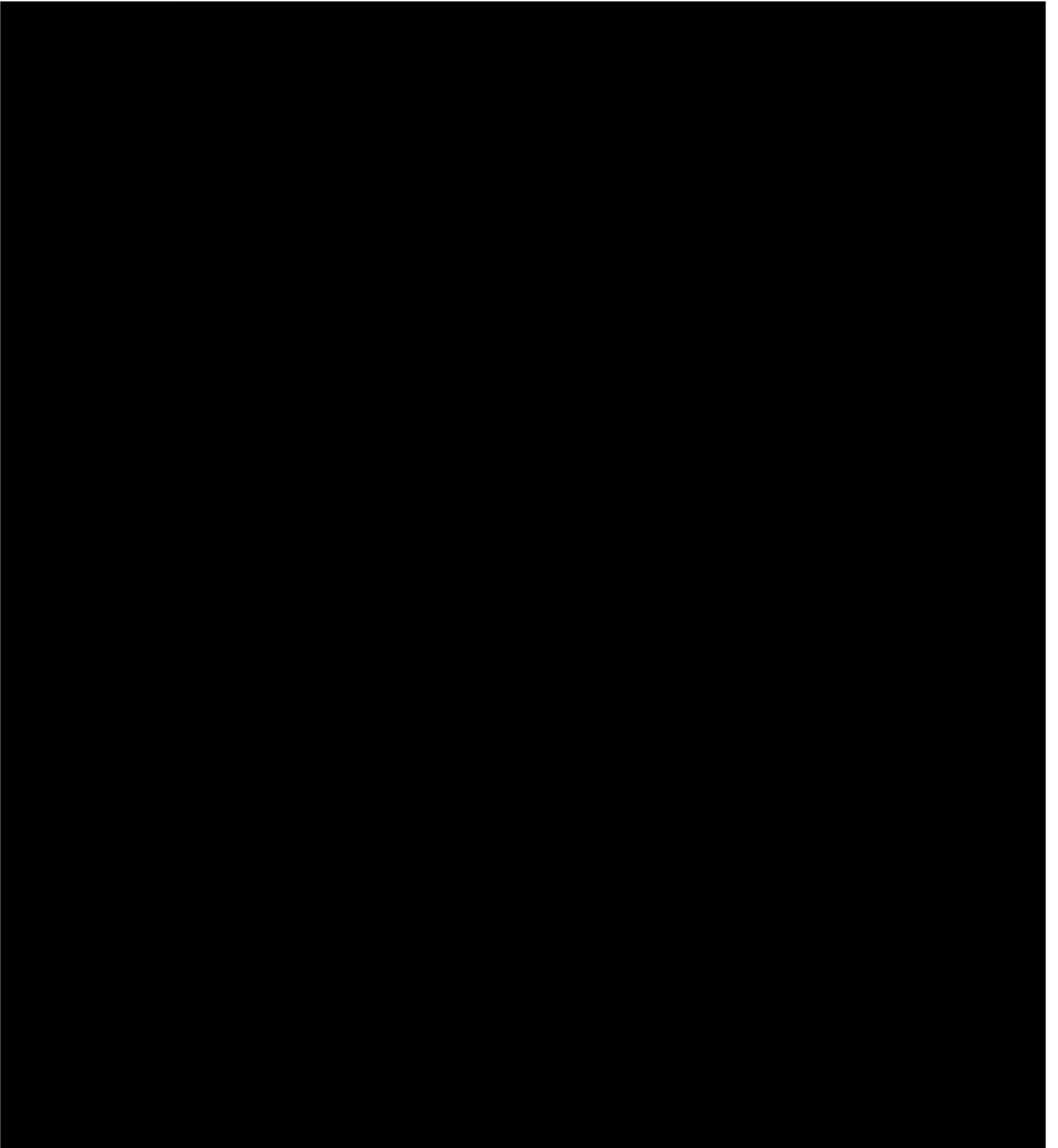
Manufacturing process information may be entitled to confidential treatment











Access to FIFRA Registration Data is restricted under FIFRA section 10(g)